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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,624	07/10/2003	Richard D. Morgan	NEB-207-US	3348

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HARRIET M. STRIMPEL; NEW ENGLAND BIOLABS, INC.
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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,624

Applicant(s)

MORGAN ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004 and 01 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 3 and 5-7 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The disclosure is objected to because of the following informalities.

Apparently the recitation on page 1, lines 11 and 15 of "5'TCC(Pu)AC-3'" and 5'-GT(Py)GGT-3'"; page 7, line 33 of "5'TCC(Pu)AC-3'"; and page 8, lines 12, 17-18 of "5'-TCC(PU)AC-3'", "5'TCC(Pu)AC-3'" and 3'AGG(Py)GT-5' are incorrect. These sequence are not complementary. The recitation on page 8, lines 1-2 are complementary but they are different from the previous sequences. After reading Tocholski, et al. (AE) and Boyd, et al. (AK), the recitation on page 8, lines 1-2 is apparently the correct one.

On page 2, line 9, page 14, line 32 and page 21, line 30 the recitation of the blank line is confusing.

On page 10, lines 13-14 and 21-22, there is no legend given as to which lanes correspond to the different DNAs for Figures 1 and 4. Apparently this is not given anywhere else in the specification.

Figures 2 and 7 are objected to as having no label on pages 2-5 and 2-7, respectively, of the figures. Before the figures will be published there will be an objection to the drawings to this effect. The figures should be resubmitted as Replacement Sheets labeled as Fig. 2A-2E and Fig. 7A-7G.

Figures 2 and 3 are objected to for the recitation of "(SEQ ID NO:)". This is confusing and indefinite.

Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 7 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/616,689. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims of 10/616,689 are drawn to DNA, a vector, a host cell and a method of using the host cell to make CstMI restriction endonuclease/methylase while claim 7 of this application is drawn to "DNA coding for an *MmeI*-like restriction enzyme". As taught in the paragraph spanning pages 21-22 of the instant specification, CstMI apparently is "an *MmeI*-like restriction enzyme" and therefore the claim 7 encompasses or is obvious over claims 1-6 of 10/616,689.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 3 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is confusing in the recitation of "*MmeI*/methyltransferase". It is not clear what the slash is intended to indicate and apparently the recitation should be "*MmeI* methyltransferase".

Claims 5-6 lack antecedent basis for "vector of claims 2 or 4". Claim 4 is drawn to "vectors", not a "vector".

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Claim 7 is indefinite in the recitation of "predetermined conditions".

What are these conditions?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification does not describe a "DNA coding for an *MmeI*-like restriction enzyme" other than perhaps *CstMI*, and the claim is not limited to this embodiment. For an application to provide an adequate written description of a nucleic acid, the inventor must be able to envision the detailed structure of the nucleic acid, i.e. have the nucleic acid in hand. A mere method of making the nucleic acid along with its biological activity is simply a wish to know the identity of any material with that activity, not a proper written description of the nucleic acid (*Fiers v. Revel* 25 USPQ 1601 (Fed. Cir, 1993)). The instant claim is drawn to a DNA that "hybridizes to at least one conserved motif of the nucleotide sequence coding for *MmeI* under predetermined conditions". If the "predetermined conditions" were low stringency of hybridization then essentially any DNA would fall within the metes and bounds of the claim. The specification does not teach one of ordinary

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skill in the art exactly what the "predetermined conditions" are nor which motifs are conserved and which are not.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant specification does not teach one of ordinary skill in the art which DNAs would meet the criteria of the instant claim and therefore to practice the claim would require undue experimentation. Exactly what conditions "predetermined conditions" encompasses is not taught nor which motifs are conserved.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts, et al. (AAB). The instant reference teaches in column 8, lines 7-22 that restriction endonucleases can be found by compiling "a database of DNA sequences that encode either a DNA methylase or a restriction enzyme". In lines 32-37 on the same column it is taught that "a significant match" is looked for in comparing DNAs. A known method of finding "a significant match" is to hybridize the two DNAs under a "predetermined condition". It would have been obvious to one of ordinary skill in the art to use the method

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taught by the instant reference to find restriction enzymes that are similar or "a significant match" to *MmeI* by hybridizing under "predetermined conditions". These restriction enzyme would by definition be "*MmeI*-like restriction enzymes". The motivation is given in the instant reference and would be to find other DNAs encoding restriction enzymes.

Claims 1 and 2 are allowed. Claim 4 is objected to as being dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the

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Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
October 28, 2005